

Wynne Health Group Weekly



FRAMING THE WEEK

This week, the House and Senate convene hearings on **COVID-19**, focused on [racial and ethnic disparities](#), [telehealth](#), [public education](#), and the [Paycheck Protection Program](#). Tomorrow, President Trump is expected to issue an executive order, outlining an array of initiatives focused on **police reform**. They include creating national standards for use-of-force and tracking police misconduct.

Under pressure to address police brutality, both parties are working expeditiously to advance their police reform proposals but whether they will reach a consensus is unclear. On Wednesday, the House Judiciary Committee will mark-up the **Justice in Policing Act of 2020 (H.R. 7120)**, backed by over 200 House members, with a vote expected later this month. Senate Republicans are expected to unveil by Wednesday their counter proposal – the **JUSTICE Act** – spearheaded by Sen. Tim Scott (R-SC).

The House Energy and Commerce (E&C) Subcommittee on Health will [continue the discussion](#) tomorrow on how COVID-19 has exacerbated **racial and ethnic health disparities**. Insufficient demographic data on COVID-19 testing, hospitalizations, and deaths for minority groups remains a frustration for Democrats. Whether the updated Report to Congress on COVID-19 testing and demographic characteristic – due today and required by the Paycheck Protection Program and Health Care Enhancement Act ([Public Law No: 116-139](#)) – will be comprehensive remains to be seen. House Energy and Commerce Committee Chairman Frank Pallone, Jr. (D-NJ) and Senate Health, Education, Labor and Pensions (HELP) Committee Ranking Member Patty Murray (D-WA) had [characterized](#) the [initial report](#) as “woefully inadequate.” Democrats may also scrutinize the recent [fact sheet](#), released by the Department of Health and Human Services (HHS) on the Trump administration’s initiatives to address the disproportionate impact of COVID-19 on Black communities and other communities of color.

As **telehealth** has transformed during the COVID-19 pandemic into a vital platform to deliver health care across the country, the national debate has shifted from whether flexibilities should be made permanent to which ones. Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma has recognized that “the genie’s out of the bottle on this one...there’s absolutely no going back.” Wednesday’s [hearing](#) in the Senate HELP Committee may provide some hints as to the scope of permanent telehealth changes that Congress envisions – such as modifications to originating and geographic site restrictions, payment parity between in-person and at-home care, and allowable telehealth services.

With his legacy top of mind, retiring Senate HELP Chairman Lamar Alexander (R-TN), is highly motivated to “ensure that the United States does not lose the gains made in telehealth.” In fact, it is one of his recommendations in his recent [white paper](#) – a starting point for a pandemic preparedness package that he wants Congress to act on this year. The Senate HELP Committee has already scheduled another [hearing](#) next Tuesday (June 23) to discuss more broadly lessons learned from the COVID-19 pandemic and to inform the forthcoming pandemic preparedness package. Comments in response to the Chairman Alexander’s white paper are due June 26.

Looking ahead, House Democrats are aiming to take up legislation to enhance the **Affordable Care Act (ACA)** around the week of July 4. Though the bill is still being crafted at the committee level, House Speaker Nancy Pelosi (D-CA) revealed that the legislation would increase advanced premium tax credits and incentivize Medicaid expansion – two proposals included in Senate Democrats’ [proposal](#) to improve health coverage in response to COVID-19.

To support the COVID-19 response, the Wynne Health Group is making its coverage of related legislative and regulatory updates publicly available. We encourage you to share our COVID-19-related summaries available [here](#).

An overview of health policy events of interest in the coming week is posted to [Policy Hub](#) and included below for your convenience.

THIS WEEK IN HEALTH POLICY

Mon. (6/15)

- **12:00pm – Hearing: COVID-19 & Education** – The House Education and Labor Committee convenes a hearing titled, “Budget Cuts and Lost Learning: Assessing the Impact of COVID-19 on Public Education.” [Details](#).
- **1:00pm-2:30pm – FDA Webinar: New Drugs** – FDA hosts a webinar on the Office of Computational Science’s (OCS) KickStart Service to discuss issues seen in Sponsor-submitted data, how industry may address these issues, and provide CDER OND policy updates for industry. [Details](#).

Tue. (6/16)

- **9:30am-1:30pm – HRSA Meeting: National Health Service Corps** – HRSA convenes a meeting of the National Advisory Council on the National Health Service Corps. [Details](#).
- **10:00am-3:30pm – CDC Meeting: Tuberculosis** – CDC convenes a meeting of the Advisory Council for the Elimination of Tuberculosis. [Details](#).
- **1:30pm-4:00pm – NIH Meeting: Pain Research** – NIH convenes a meeting of the Interagency Pain Research Coordinating Committee to discuss COVID-19, the NIH HEAL Initiative, and the SUPPORT Act. [Details](#).
- **2:30pm – Hearing: Policing** – The Senate Judiciary Committee convenes a hearing titled, “Police Use of Force and Community Relations.” [Details](#).

Wed. (6/17)

- **8:30am-4:30pm – ONC Meeting: Health IT** – The Office of the National Coordinator for Health Information Technology (ONC) convenes a meeting of the Health IT Advisory Committee. [Details](#).
- **10:00am – Markup: Policing** – The House Judiciary Committee convenes a markup of Justice in Policing Act of 2020 (H.R. 7120). [Details](#).
- **10:00am – Hearing: Telehealth** – The Senate Health, Education, Labor and Pensions Committee convenes a hearing titled, “Telehealth: Lessons from the COVID-19 Pandemic.” [Details](#).
- **10:00am – Hearing: Small Businesses** – The House Small Business Committee convenes a hearing titled, “Paycheck Protection Program: Loan Forgiveness and Other Challenges.” [Details](#).
- **10:00am – Hearing: Trade Policy** – The House Ways and Means Committee convenes a hearing titled, “The 2020 Trade Policy Agenda,” featuring U.S. Trade Representative Robert E. Lighthizer. [Details](#).

- **11:00am-7:00pm – HHS Meeting: Nutrition** – HHS convenes a meeting of the Dietary Guidelines Advisory Committee to finalize their advisory report on Dietary Guidelines. [Details.](#)
- **11:30am – Hearing: COVID-19 & Health Disparities** – The House Energy and Commerce Subcommittee on Health convenes a hearing titled, “Health Care Inequality: Confronting Racial and Ethnic Disparities in COVID-19 and the Health Care System.” [Details.](#)
- **3:00pm – Hearing: Trade Policy** – The Senate Finance Committee convenes a hearing titled, “The President’s 2020 Trade Policy Agenda,” featuring U.S. Trade Representative Robert E. Lighthizer. [Details.](#)

Thurs. (6/18)

- **1:00pm-2:00pm – NIHCM Webinar: COVID-19 & Housing** – The National Institute for Health Care Management Foundation (NIHCM) hosts a webinar titled, “Homelessness & COVID-19: A Merger of Two Epidemics.” [Details.](#)

Fri. (6/19)

- No events scheduled.

Additional Multi-Day Events

- **June 17-June 18 – HHS Meeting: Health Statistics** – HHS convenes a virtual meeting of the National Committee on Vital and Health Statistics to discuss several health data policy topics and refine its workplan for the upcoming 12-month period. [Details.](#)
- **June 17-June 18 – HRSA Meeting: Infant Mortality** – HHS convenes a meeting of the Secretary’s Advisory Committee on Infant Mortality. [Details.](#)
- **June 17-June 18 – FDA Meeting: New Products** – FDA convenes a meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee to consider: (1) SP 2577, presentation by Salarius Pharmaceuticals, Inc. and (2) Marizomib, presentation by Celgene International II Sàrl, a wholly owned subsidiary of Bristol-Myers Squibb. [Details.](#)

FEATURED WHG ANALYSIS

- **WHG COVID-19 Government Response Catalogue** – Updated 6/8/20 – In the Policy Hub Insight Bank [here.](#)
- **Chart: Key Federal COVID-19 Funding Opportunities for Providers & Hospitals** – Updated 5/29/20 – In the Policy Hub Insight Bank [here.](#)
- **Chart: Compilation of Federal COVID-19 Telehealth Flexibilities** – In the Policy Hub Insight Bank [here.](#)
- **Chart: Key Federal COVID-19 Funding Opportunities for Employers** – Last Updated 4/24/20 – In the Policy Hub Insight Bank [here.](#)
- **Chart: Key Federal COVID-19 Funding Opportunities for State and Local Government** – Last Updated 4/24/20 – In the Policy Hub Insight Bank [here.](#)

CONGRESSIONAL LOOKBACK

Fri. (6/12)

- **Senate Finance Committee Chairman Chuck Grassley (R-IA)** and Ranking Member Ron Wyden (D-OR) wrote to Health and Human Services (HHS) Secretary Alex Azar, urging the Department to establish a comprehensive public database of coronavirus relief funds distributed to health care providers. [Details.](#)

Tue. (6/9)

- **Senate HELP Committee Chairman Lamar Alexander (R-TN)** released a [white paper](#), “Preparing for the Next Pandemic” – a starting point for a legislative package to bolster the federal government’s [public health](#) infrastructure and capacity. Responses are due by June 26. [Details](#).
- **The Senate Committee on Homeland Security and Governmental Affairs** [convened](#) a hearing to examine the federal government’s procurement and distribution of medical supplies during the COVID-19 pandemic. [Details](#).
- **The House Oversight and Reform Subcommittee** on Economic and Consumer Policy [convened](#) a briefing to discuss the role that serological antibody tests play in the response to the coronavirus pandemic, recommendations and limitations for their use, and federal policy. [Details](#).

REGULATORY LOOKBACK

Fri. (6/12)

- **HHS OCR** issued a [final rule](#) ([fact sheet](#); [press release](#)) under section 1557 of the Affordable Care Act that repeals the 2016 definition of sex discrimination, rolling back previously finalized nondiscrimination protections for transgender patients and women seeking abortions. [Details](#).

Wed. (6/10)

- **USPSTF** [issued](#) a final recommendation statement for the screening of unhealthy drug use among adults and adolescents. The task force recommended screening by asking questions about unhealthy drug use in adults age 18 years and older. [Details](#).

Tue. (6/9)

- **CMS** released new [guidance](#) to providers in supporting the administration’s initiative to continue reopening health care facilities in the U.S. As CMS notes, the recommendations apply only to those providers within areas in Phase II of reopening. [Details](#).
- **HHS** announced an additional distribution of \$25 billion from the COVID-19 Provider Relief Fund, aimed at safety net hospitals and Medicaid and CHIP providers. [Details](#).
- **FDA** and the National Telecommunication and Information Administration (NTIA) [announced](#) a new pilot program to help reduce the availability of unapproved opioids illegally sold online. [Details](#).

Mon. (6/8)

- **FDA** [issued](#) revised Emergency Use Authorizations (EUAs) to specify which respirators are appropriate for decontamination and reuse, based on new evidence. [Details](#).
- **FDA** [issued](#) final guidance on Institutional Review Board (IRB) review of individual patient expanded access requests for investigational drugs and biologic products during the COVID-19 public health emergency (PHE). [Details](#).

COMMENT & APPLICATION DEADLINES

- **June 16:** CDC issued a [request for comment](#) soliciting input on and experiences with pain and pain management to inform the agency’s assessment of the need for updating or expanding the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain. [Details](#).
- **June 17:** USDA extended the comment period on the proposed rule titled, “Employment and Training Opportunities in the Supplemental Nutrition Assistance Program (SNAP).” [Details](#).

- **June 17:** CDC announced a funding opportunity to provide Pediatric Environmental Health Specialty Units (PEHSUs) with supplemental funding to support their COVID-19 response efforts. [Details.](#)
- **June 21:** OASH within HHS seeks public comment regarding Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act, addressing recommendations for maintaining an adequate national blood supply. [Details.](#)
- **June 21:** FDA seeks comments on draft guidance on technical considerations for demonstrating reliability of emergency-use injectors. [Details.](#)
- **June 27:** ASPR [announced](#) the establishment of the National Advisory Committee on Children and Disasters (NACCD) and a request for nominations for members. [Details.](#)
- **June 30:** NIH issued two requests for letters of interest (LOIs): 1) LOIs for National Cancer Institute (NCI) Molecular Analysis for Therapy Choice (MATCH); and 2) LOIs for pediatric-focused NCI-MATCH. LOIs are due June 30. [Details.](#)
- **June 30:** CDC re-opened the public comment period for the proposed update of the 2006 “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings.” [Details.](#)
- **June 30:** The White House Office of National Drug Control Policy (ONDCP) issued an [Advance Notice of Proposed Rulemaking](#), soliciting comments on proposed criteria for designating emerging drug threats. [Details.](#)
- **July 2:** CMS issued a [proposed rule](#) to amend the Department of Health and Human Services’ ACA risk adjustment data validation (HHS-RADV) program. [Details.](#)
- **July 3:** AHRQ [announced](#) a request for nominations for members. AHRQ advises the Secretary of HHS and produces evidence to make health care safer, higher quality, more accessible, equitable, and affordable. [Details.](#)
- **July 7:** CMS is accepting comments on an interim final rule with comment period (IFC) containing a second set of wide-reaching regulatory changes and flexibilities for providers in response to the COVID-19 pandemic. [Details.](#)
- **July 8:** The Office of the Assistant Secretary for Health (OASH) issued a [request for information](#) (RFI) to better understand how stakeholders across the healthcare system have defined “resilience,” including in the use of data, analytic methods, and proven indicators. [Details.](#)
- **July 10:** CMS is accepting comments on the FY 2021 inpatient prospective payment system (IPPS) and long-term care hospital prospective payment system (LTCH PPS) proposed rule. [Details.](#)
- **July 14:** CDC [issued](#) a request for information regarding personnel and the retention of next generation sequencing (NGS) data in clinical and public health laboratories. [Details.](#)
- **July 31:** FDA [issued](#) a request for information (RFI) on rare disease clinical trials. [Details.](#)
- **Aug. 3:** CDC [announced](#) it is seeking nominations for individuals to serve as members of the Healthcare Infection Control Practices Advisory Committee (HICPAC). [Details.](#)
- **Aug. 3:** FDA is accepting comments on 25 new draft PSGs and 24 revised draft product-specific guidances (PSGs). [Details.](#)
- **Aug. 20:** FTC is requesting public comment on its Health Breach Notification Rule, which is now subject to the agency’s 10-year rule review cycle. [Details.](#)